

voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 0023.1 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. This rule is categorically excluded from certain documentation requirements under figure 2–1, paragraph (34)(g), of the Instruction because the rule involves establishment of a safety zone. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T11–244 to read as follows:

§ 165.T11–244 Safety Zone; Coast Guard Use of Force Training Exercises, San Pablo Bay, CA.

(a) *Location.* The following area is a safety zone: All waters of San Pablo Bay from the surface to the seafloor, encompassed by lines connecting the following points: Beginning at 38°05′11″ N, 122°22′10″ W; thence to 38°03′44″ N, 122°20′12″ W; thence to 38°00′41″ N, 122°25′28″ W; thence to 38°01′45″ N, 122°26′38″ W; thence returning to 38°05′11″ N, 122°22′10″ W (NAD 83).

(b) *Effective period.* The Coast Guard will notify the public via a Broadcast to Mariners prior to the activation of this safety zone. The Coast Guard may activate the safety zone anytime from 9 a.m. through 11:59 p.m. every Tuesday, Thursday, and Friday, every week of every month. If the exercises conclude prior to the scheduled termination time, the Coast Guard will cease enforcement of this safety zone and will announce that fact via Broadcast Notice to Mariners. Persons and vessels may also contact the Coast Guard to determine the status of the safety zone on VHF–16 or the 24-hour Command Center via telephone at (415) 399–3547.

(c) *Definitions.* As used in this section, designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

(d) *Regulations.* (1) Under the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the COTP or the COTP's designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP's designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or the COTP's designated representative. Persons and vessels may request permission to enter the safety zone on VHF–16 or the 24-hour Command Center via telephone at (415) 399–3547.

Dated: October 16, 2009.

P.M. Gugg,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

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BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2008–0252; FRL–8436–8]

RIN 2070–AB27

Proposed Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for two chemical substances which were the subject of premanufacture notices. The two substances are identified generically as multi-walled carbon nanotubes (P–08–177) and single-walled carbon nanotubes (P–08–328). These substances are subject to TSCA section 5(e) consent orders issued by EPA. The consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs on these substances are based on and consistent with the provisions in the underlying consent orders. The proposed SNURs designate as a “significant new use” the absence of the protective measures required in the corresponding consent orders. This action would require persons who intend to manufacture, import, or process either of these two substances for an activity that is designated as a significant new use by this proposed rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: Comments must be received on or before December 7, 2009.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2008–0252, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania

Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2008-0252. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2008-0252. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm.

3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For general information contact:* Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Jim Alwood, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8974; e-mail address: alwood.jim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substances contained in this proposed rule. Potentially affected entities may include, but are not limited to:

- Manufacturers, importers, or processors of one or both subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the

technical person listed under **FOR FURTHER INFORMATION CONTACT**.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28 (the corresponding EPA policy appears at 40 CFR part 707, subpart B). Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to a final SNUR must certify their compliance with the SNUR requirements. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after December 7, 2009 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA is proposing significant new use rules (SNURs) under section 5(a)(2) of TSCA for two chemical substances which were the subject of premanufacture notices (PMNs). The two substances are identified generically as multi-walled carbon nanotubes (P-08-177) and single-walled carbon nanotubes (P-08-328). These substances are subject to TSCA section 5(e) consent orders issued by EPA, which require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs on these substances are based on and consistent with the provisions in the underlying consent orders. The proposed SNURs designate as a "significant new use" the absence of the protective measures required in the corresponding consent orders. These SNURs would require persons who intend to manufacture, import, or process either of these two substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

In the **Federal Register** of June 24, 2009 (74 FR 29982) (FRL-8417-6), EPA issued direct final SNURs on these two substances in accordance with the procedures at § 721.160(c)(3)(i). EPA received a notice of intent to submit adverse comments on these SNURs. Therefore, as required by § 721.160(c)(3)(ii), in the **Federal Register** of August 21, 2009 (74 FR 42177) (FRL-8433-9), EPA withdrew the direct final SNURs and is now issuing this proposed rule on the two substances. The record for the direct final SNURs on these substances was established as docket EPA-HQ-OPPT-2008-0252. That record includes information considered by the Agency in developing the direct final rules and the notice of intent to submit adverse comments.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. The mechanism for reporting under this requirement is established under § 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Chemical importers are subject to the TSCA section 13 (15 U.S.C. 1612) import certification requirements promulgated at 19 CFR 12.118 through 12.127, and 19 CFR 127.28 (the corresponding EPA policy appears at 40 CFR part 707, subpart B). Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemical substances subject to a final SNUR must certify their compliance with the SNUR requirements. In addition, any persons who export or intend to export a chemical substance identified in a final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2612 (b)) (see § 721.20),

and must comply with the export notification requirements in 40 CFR part 707, subpart D.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the two chemical substances that are the subject of these proposed SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the above four factors listed in TSCA section 5(a)(2).

IV. Substances Subject to this Proposed Rule

EPA is proposing to establish significant new use and recordkeeping requirements for two chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name if the specific name is claimed as CBI).
- CAS number (if assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) consent order.
- Toxicity concerns.
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VII. for more information).
- CFR citation assigned in the regulatory text section of this proposed rule.

The regulatory text section of this proposed rule specifies the activities designated as significant new uses. Certain new uses, including production limits and other uses designated in this

proposed rule, may be claimed as CBI. Unit VIII. discusses a procedure companies may use to ascertain whether a proposed use constitutes a significant new use.

This proposed rule concerns two PMN substances that are subject to "risk-based" consent orders under TSCA section 5(e)(1)(A)(ii)(I) where EPA determined that activities associated with the PMN substances may present unreasonable risk to human health. Those consent orders require protective measures to limit exposure or otherwise mitigate the potential unreasonable risk. The so-called proposed "5(e) SNURs" on these PMN substances are issued pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The proposed 5(e) SNURs would designate as a "significant new use" the absence of the protective measures required in the corresponding consent orders.

PMN Number P-08-177

Chemical name: Multi-walled carbon nanotubes (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: September 1, 2009 (amended).

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as a property modifier in electronic applications and as a property modifier in polymer composites. The order was issued under sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA. Based on test data on analogous respirable, poorly soluble particulates and on other carbon nanotubes (CNTs), EPA believes that the PMN substance may cause lung effects. To protect against this risk, the consent order requires use of a National Institute for Occupational Safety and Health (NIOSH)-approved full-face respirator with N-100 cartridges. Based on physical properties of the PMN substance, EPA believes it may cause health effects via dermal exposure. To protect against this risk, the consent order requires that workers wear gloves and protective clothing impervious to the chemical substance. The consent order also prohibits any predictable or purposeful release of the PMN substance into the waters of the United States. The proposed SNUR would designate as a "significant new use" the absence of these protective measures. *Toxicity concern:* There is a concern for lung health effects based on data for poorly soluble particulates and for other CNTs, and for lung irritation based on particle size.

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity study in rats (OPPTS Harmonized Test Guideline 870.3465 or Organisation for Economic Co-operation and Development (OECD) 413 test guideline) with a post exposure observation period of up to 3 months, including bronchoalveolar lavage fluid (BALF) analysis; and certain material characterization data would help characterize possible effects of the PMN substance. In the consent order, the PMN submitter has agreed not to exceed a specified production volume or production time limit (whichever comes first) without performing these tests.

CFR citation: 40 CFR 721.10155.

PMN Number P-08-328

Chemical name: Single-walled carbon nanotubes (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: September 1, 2009 (amended).

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as a property modifier in electronic applications and as a property modifier in polymer composites. The order was issued under sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA. Based on test data on analogous respirable, poorly soluble particulates and on other carbon nanotubes (CNTs), EPA believes that the PMN substance may cause health effects. To protect against this risk, the consent order requires use of a NIOSH-approved full-face respirator with N-100 cartridges. Based on physical properties of the PMN substance, EPA believes it may cause health effects via dermal exposure. To protect against this risk, the consent order requires that workers wear gloves and protective clothing impervious to the chemical substance. The consent order also prohibits any predictable or purposeful release of the PMN substance into the waters of the United States. The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Toxicity concern: There is a concern for health effects based on data for poorly soluble particulates and for other CNTs, and for lung irritation based on particle size.

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity study in rats (OPPTS Harmonized Test Guideline 870.3465 or OECD 413 test guideline) with a post exposure observation period of up to 3 months, including BALF analysis; and certain material characterization data

would help characterize possible effects of the PMN substance. In the consent order, the PMN submitter has agreed not to exceed a specified production volume or production time limit (whichever comes first) without performing these tests.

CFR citation: 40 CFR 721.10156.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for these two chemical substances, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the human health effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The proposed SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders including the recent modifications to the consent orders. These proposed SNURs are issued pursuant to § 721.160.

B. Objectives

EPA is proposing these SNURs for specific chemical substances that have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this proposed rule:

- EPA would receive notice of any person's intent to manufacture, import, or process a listed chemical substance for the described significant new use before that activity begins.
- EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for the described significant new use.
- EPA would be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.
- EPA would ensure that all manufacturers, importers, and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the

chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at <http://www.epa.gov/opptintr/newchems/pubs/invntory.htm>.

VI. Applicability of Proposed Rule to Uses Occurring Before Effective Date of the Final Rule

To establish a significant "new" use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review and are subject to TSCA section 5(e) consent orders. The PMN submitters are prohibited by these TSCA section 5(e) consent orders from undertaking activities which EPA is proposing as significant new uses. EPA solicits comments on whether any of the uses proposed as significant new uses are ongoing.

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements because a person could defeat the SNUR by initiating the significant new use before the rule became final, and then argue that the use was ongoing before the effective date of the final rule. Thus, persons who begin commercial manufacture, import, or processing activities with the chemical substances that would be regulated as a "significant new use" through this proposed rule, must cease any such activity before the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

EPA has promulgated provisions to allow persons to comply with this proposed SNUR before the effective date. If a person were to meet the conditions of advance compliance under § 721.45(h), the person would be considered exempt from the requirements of the SNUR.

VII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN, except where the chemical substance subject to the SNUR is also

subject to a test rule under TSCA section 4 (see TSCA section 5(b)). Persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see § 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV lists those tests. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Many OPPTS Harmonized Test Guidelines are now available on the Internet. Please go to <http://www.epa.gov/oppts> and select "Test Methods and Guidelines" on the left-side navigation menu. The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>.

In the TSCA section 5(e) consent orders for the two chemical substances regulated under this proposed rule, EPA has established production volume limits in view of the lack of data on the potential health risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent TSCA section 5(e) consent orders, each PMN submitter is required to submit each study at least 14 weeks (earlier TSCA section 5(e) consent orders required submissions at least 12 weeks) before reaching the specified production limit. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit IV. The SNURs contain the same production volume limits as the TSCA section 5(e) consent orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture, import, or processing.

The recommended tests may not be the only means of addressing the potential risks of the chemical substance. However, SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA will take action under TSCA

section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VIII. Procedural Determinations

By this action, EPA is proposing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI. This rule cross-references § 721.1725(b)(1) and is similar to that in § 721.11 for situations where the chemical identity of the chemical substance subject to a SNUR is CBI. This procedure is cross-referenced in each SNUR that includes specific significant new uses that are CBI.

Under these procedures a manufacturer, importer, or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer, importer, or processor must show that it has a *bona fide* intent to manufacture, import, or process the chemical substance and must identify the specific use for which it intends to manufacture, import, or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture, import, or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers, importers, and processors can combine the *bona fide* submission under the procedure in § 721.1725(b)(1) with that under § 721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission

would not be a significant new use, i.e., the use does not meet the criteria specified in the rule for a significant new use, that person can manufacture, import, or process the chemical substance so long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the aggregate annual production volume does not exceed that identified in the *bona fide* submission to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use.

IX. SNUN Submissions

As stated in Unit II.C., according to § 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in § 720.50. SNUNs must be mailed to the Environmental Protection Agency, OPPT Document Control Office (7407M), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Information must be submitted in the form and manner set forth in EPA Form No. 7710-25. This form is available from the Environmental Assistance Division (7408M), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001 (see § 721.25 and 720.40). Forms and information are also available electronically at <http://www.epa.gov/opptintr/newchems/pubs/pmnforms.htm>.

X. Economic Analysis

EPA evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substances during the development of the direct final rule. The Agency's complete economic analysis is available in the public docket.

XI. Statutory and Executive Order Reviews

A. Executive Order 12866

This proposed rule would establish SNURs for several new chemical substances that were the subject of PMNs and TSCA section 5(e) consent orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory*

Planning and Review (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA would amend the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this proposed rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action would not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of these SNURs would not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is discussed in this unit. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a "significant new use." Because these uses are "new," based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of over 1,000 SNURs, the Agency receives on average only 5 notices per year. Of those SNUNs submitted from 2006-2008, only one appears to be from a small entity. In addition, the estimated reporting cost for submission of a SNUN (see Unit IX.) is minimal regardless of the size of the firm. Therefore, the potential economic impacts of complying with these SNURs are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government would be impacted by this proposed rule. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

E. Executive Order 13132

This action would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly or uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this proposed rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This proposed rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

In addition, since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and*

Low-Income Populations (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: October 26, 2009.

Wendy C. Hamnett,

Acting Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721—[AMENDED]

1. The authority citation for part 721 would continue to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. By adding new § 721.10155 to subpart E to read as follows:

§ 721.10155 Multi-walled carbon nanotubes (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified generically as multi-walled carbon nanotubes (PMN P-08-177) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(5) (National Institute for Occupational Safety and Health (NIOSH)-approved air-purifying, tight-fitting full-face respirator equipped with N100 filters), (a)(6)(i), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (k) and (q).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

3. By adding new § 721.10156 to subpart E to read as follows:

§ 721.10156 Single-walled carbon nanotubes (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified generically as single-walled carbon nanotubes (PMN P-08-328) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.*

Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(5) (National Institute for Occupational Safety and Health (NIOSH)-approved air-purifying, tight-fitting full-face respirator equipped with N100 filters), (a)(6)(i), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (k) and (q).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

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DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Parts 223 and 224**

[Docket No. 0812291651-91321-02]

RIN 0648-XM05

Endangered and Threatened Wildlife and Plants; Endangered Species Act Listing Determination for Atlantic Wolffish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of a listing determination and availability of a status review document.

SUMMARY: After we, NMFS, received a petition to list Atlantic wolffish